

Applicants: Christophorus Meijer et al.  
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Filed: September 29, 2005  
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### REMARKS

This Amendment responds to the Office Action dated May 16, 2008, in which the Examiner rejected claims 11-13, 15 and 17. Claims 1-10, 14, 16, 18-28 have been withdrawn without prejudice pursuant to a restriction requirement. In response to the rejection applicants have amended claims 11 and 17. Reconsideration and reexamination is respectfully requested in view of the foregoing amendments and the following remarks.

Applicants have addressed the §112, second paragraph, claim rejections of claims 11-13, 15-17 by amending claims 11 and 17. Applicants submit that the rejections may now be withdrawn.

The Examiner also rejects claims 11-13, 15 and 17 as anticipated by Reeves. The Examiner asserts that Reeves allegedly teaches a method of detecting proliferative cells using TSLC1, which the Examiner asserts covers all types of cancer including HPV-induced cancer or precursor lesions. Alternatively, the Examiner asserts that Reeves discloses treatment of "cancer," which includes all type of cancer. The Examiner also relies on the inherency doctrine, given the alleged identity or substantial identity of the cited art and the claimed invention.

Applicants respectfully request reconsideration of the rejection. First, applicants submit that the Examiner's broad reading of the reference and its subsequent application to the claim is fundamentally flawed. Reeves discuss three types of cancers only, all of which are unrelated to HPV induced cancer: lung cancer, pancreatic cancer, and liver cancer. Reeves lacks any mention, much less an enabling disclosure, of the HPV induced cancers. It is elementary patent law that a reference must provide an enabling disclosure of the claimed invention (not some vaguely related group of diseases) to be considered

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anticipating. The document must disclose within the four corners thereof a written description of the claimed invention, and must additionally teach a person of ordinary skill in the art how to make and use the claimed invention. In the absence of such an enabling disclosure, the reference is not even a proper prior art citation against the invention. The Examiner has overlooked this vital point.

Further, it is well-settled that disclosure of a genus, here "proliferative diseases" or "cancer" does not amount to disclosure or anticipation of each species covered by the genus. The patentee may claim a genus covers a specie for infringement purposes, but the converse is simply not true, particularly when there is no way to determine a priori whether a particular species will be operative, and when there is no enabling disclosure of HPV induced cancer or precancerous lesions. Applicants submit that the scattergun assertion that "proliferative diseases" or "cancer" anticipates each known form of cancer, including the claimed HPV-induced cancer, regardless of whether the reference even mentions that disease is wide of the mark. Applicants respectfully request therefore that the pending anticipation rejection should be reconsidered and withdrawn.

Moreover, for many of the same reasons, the claimed invention cannot be said to be obvious over Reeves either. The vague reference in Reeves to "proliferative diseases" or "cancer" would not lead a person of ordinary skill to consider the claimed invention obvious. Instead, a person of ordinary skill would see the Reeves data relating to lung, liver, and pancreatic cancers, but would be unable to extrapolate therefrom any suggestion or motivation to use TSLC1 in connection with the claimed invention on HPV induced cancers. Only using the hindsight provided by the present application, where applicants

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have discovered to their own surprise that the claimed invention works on HPV induced cancers, could the Examiner suggest that the claimed invention would be obvious.

In addition, the claimed invention provides unexpected results. As set forth in the specification, the published literature states that TSLC1 gene silencing has been detected in 40% of lung cancers, 33% of breast cancers, 27% of primary pancreatic adenocarcinomas, and 34% of nasopharyngeal carcinoma (specification, page 30, lines 15-23). In the claimed invention, the analysis of cervical cancer cell lines surprisingly reveals that TSLC1 gene silencing occurred in as many of 91% of cell lines (specification, page 9, lines 15-23). In adenocarcinomas of the lung, the reported literature associates a reduced TSLC1 expression with poor prognosis for the patient (specification, page 30, line 24 to page 31, line 2). It is elementary that a species is patentable over a genus when there are unexpected results.

In all respects then, the Examiner's strenuous reliance on Reeves seems misplaced. The reference lacks any mention of the claimed invention, and indeed the claimed invention unexpectedly displays 2-3 times the TSLC1 gene suppression found in other cancers that have been reported in the literature. Moreover, the existence of a reference that discloses both a low TSLC1 suppression rate in adenocarcinoma of the lung and an associated poor prognosis for the patient "teaches away" from investigating TSLC1 use in HPV induced cervical cancer. Applicants submit that they have shown that the claimed invention is neither anticipated nor rendered obvious by Reeves, and respectfully requests that a notice of allowability of the pending claims as amended be issued forthwith.

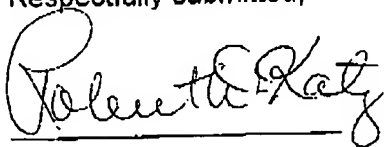
The Director is authorized to charge any fee required in connection with this

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response to Deposit Account No. 03-3125. If any extension is required in connection with the filing of this response, applicants hereby request same and authorize the fee therefor to be charged to Deposit Account No. 03-3125.

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Respectfully submitted,

A handwritten signature in black ink, appearing to read "Robert D. Katz", written over a horizontal line.

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